## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Stamm et al

Application No. 10/665,520 Group Art Unit: 1615

Filed: September 22, 2003 Examiner: Sheikh

For: Processes For Producing Fenofibrate Compositions

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

## **Information Disclosure Statement**

Pursuant to 37 CFR §§ 1.56, 1.97 and 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449 Form. A copy of the Non Patent Literature Documents and the Foreign Patent Documents is attached hereto.

Applicants direct the Examiner's attention to:

- (a) Cite No. 1 on PTO-1449 Form No. 1 of 9, the dissolution profile on page
   12 at Table VII in Laboratoires Fournier's undated document entitled
   "Fenofibrate Tablets 54-160 MG Dissolution Test Conditions
   Development Studies, Dissolution Test Specification Recommendations."
- (b) Cite No. 24 on PTO-1449 Form 3 of 9, the Declaration under 37 CFR § 1.132 by Phillippe Reginault filed in US Application No. 10/288,425 on March 7, 2005.
- (c) On PTO-1449 Form 5 of 9, the Declaration under 37 CFR § 1.132 by
  Pascale Blouquin with attached Exhibits 1-5 filed in US Application No.
  09/899,026 on March 7, 2005; Laboratoires Fournier's Lab Notebook No.
  1 from 18 February 1997 to 15 May 1997; Laboratoires Fournier's Lab
  Notebook No. 2 from 16 May 1997 to 30 July 1997; ACCES JADDO1 CCCCCOOR 220261 10665520
- (d) In re TriCor Indirect Purchaser Antitrust Litigation, District of Delaware, Civil Action No. 05-360.
- (e) CVS Pharmacy, Inc. et al. v. Abbott Laboratories et al, District of Delaware, 1:05-cv-00605-KAJ.

Information Disclosure Statement Page 2 of 2

> Walgreen Co. et al v. Abbott Laboratories et al, District of Delaware, (f)

> > 1:05-cv-00404-KAJ.

Pacificare Health Systems, Inc. v. Abbott Laboratories et al, District of (g)

Delaware, 1:05-cv-00591-KAJ.

Painters District Council No. 30 Health and Welfare Fund et al v. Abbott (h)

Laboratories et al, District of Delaware, 1:05-cv-00360-KAJ.

(i) Louisiana Wholesale Drug Company, Inc. v. Abbott Laboratories et al,

District of Delaware, 1:05-cv-00340-KAJ;

(j) Paul T. Tegan v. Abbott Laboratories et al, Central District of California,

2:05-cv-05410-GAF-AJW.

The submission of this Information Disclosure Statement does not represent that a search

has been made and does not constitute an admission that the listed documents, oppositions and/or

litigations are material to patentability or that the listed documents are prior art.

This Information Disclosure Statement is being filed after the mailing date of a first

office action on the merits, but before a final office action or a notice of allowance. Accordingly,

the Commissioner is authorized to charge the fee of \$180 to Deposit Account No. 22-0261. The

Commissioner is authorized to charge any other necessary fees or credit any overpayments to

Deposit Account No. 22-0261.

Applicants respectfully request that the PTO return an initialed copy of the PTO-1449

Form with the next communication from the Office.

Respectfully submitted,

Edward D. Grieft

Registration No. 38,89

Date: May 9, 2006

Venable LLP

575 7<sup>th</sup> Street, NW Washington, DC 20004

Phone: 202-344-4382

Fax: 202-344-8300

PTO/SB/08B (07-05)

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Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known 1449/PTO Substitute for **Application Number** 520 INFORMATION DISCLOSURE Filing Date September 22, 2003 STATEMENT BY APPLICANT **First Named Inventor** Stamm Art Unit 1615 (Use as many sheets as necessary) **Examiner Name** Sheikh

**Attorney Docket Number** 

Sheet

of

Examiner	Cite	NON PATENT LITERATURE DOCUMENTS  Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	
Initials*	No.1	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	1	Laboratoires Fournier undated document entitled "Fenofibrate Tablets 54-160 mg Dissolution Test Conditions Development Studies, Dissolution Test Specification Recommendations"	
- 11 - 11 - 11	2	"Second Amended Answer, Affirmative Defenses, and Counterclaims" filed by Teva on 7-29-2005 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc. DE, CA No. 02-1512.	
	3	"First Amended Counterclaims" filed by Impax on 9-23-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	
	4	"Amended Complaint" filed by CVS Pharmacy et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340.	
	5	"Amended Complaint" filed by Walgreen Co. et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340.	
	6	"Amended Complaint" filed by Painters' District Council No. 30 et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340.	
	7	"Amended Complaint" filed by Louisiana Wholesale Drug Co. et al on 10-3-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340.	
	8	"Defendant's Responses to Plaintiffs Interrogatories" filed by Impax on 8-6-2003 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	
	9	"Amended Answer" filed by Impax on 1-4-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	
	10	"Reply Memorandum" filed by Impax on 2-25-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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INF	ORMATION	DIS	CLOSURE	Filing Date					
STATEMENT BY APPLICANT			First Named Inventor	Stamm					
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	1030 da many ano			Examiner Name	Sheikh				
Sheet	2	of	9	Attorney Docket Number	2	24616			

		NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²		
	11	"Memorandum Opinion" by District Judge Jordan dated 5-6-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.			
	12	"Opening Brief in Support of Motion for Summary Judgment" by Teva filed on 12-23-2004 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512.			
	13	"Opening Brief in Support of Motion for Summary Judgment" by Teva filed on 12-10-2004 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512.			
"Memorandum Opinion" by District Judge Jordan dated 5-6-2005 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1					
	15	Opposition to European Patent No. 1 273 293 filed 9-2-2005 by Ethypharm (French Language Docuement).			
	16	Opposition to Israel Patent No. 130790 filed 5-4-2005 by Teva; and Remarks in Response to Oppostion filed on 9-23-2005 (English language translations).	1		
	17	Munoz et al, Atherosclerosis, 110(Suppl.):S45-S48 (1994).			
	18	Pharmaceutical Pelletization Technology, Marcel Dekker, Inc., Volume 37, pages 1-13; 160-161; and 234-235 (1989).			
	Modern Pharmaceutics, Third Edition, Marcel Dekker, Inc., apges 131-133 and 335-356 (1996).				
	20	Pharmaceutical Dosage Forms, Tablets, Second Edition, Marcel Dekker, Inc., pages 5-28; 88-107; 133; 142; 160-165; and 260-267 (1989).			

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Examiner	-	Date	
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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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STATEMENT BY APPLICANT			PPLICANT	First Named Inventor	Stamm		
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Sheet	3	of	9	Attorney Docket Number	224616		

		NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), ti the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-in number(s), publisher, city and/or country where published.					
,	21	Shepherd Atherosclerosis, 110(Suppl.)S55-S63 (1994).				
	22	Adkins et al, Drugs, 54(4):615-633 (October 1997).				
	Letter from Teva/Novopharm to Fournier Pharma Inc. regarding Invalidity and Ambigu of Canadian Patent Nos. 2,219,475 and 2,372,576 (pages 1-15)(September 19, 2005)					
	Declaration under 37 CFR 1.132 by Phillippe Reginault filed in US Application No. 10/288,425 on March 7, 2005.  Pharmaceutical Pelletization Technology, Ghebre-Sallassie, Ed., Marcel Dekker, Inc., New York, Chapters 7 and 10 (1989).					
	26	Handbook of Pharmaceutical Excipients, 2nd Ed., pages 48-87, 141-144, 229-232, 252-261, 280-282, 392-401, 424-427, 448-450, 462-469, 491-493 (1994).				
	27	Remington's Pharmaceutical Sciences, 18th Ed., pages 1633-1665 (1985).				
	European Pharmacopoeia, 3rd Ed., pages xiii-xvii and 127-131 (1996).					
	The United States Pharmacopoeia, Vol. 23, pages liv-lvi, 1791-1793, 1924-1938 (1994).					
	30	CRC Handbook of Chemistry & Physics, 73rd Ed., Chapter 15, page 32 (1992).				

Examiner	Date	
Signature	Considered	

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Substitute for form 1443/FTO	Application Number	10/665,520			
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STATEMENT BY APPL	CANT First Named Inventor	Stamm			
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(000 20 1121) 511002 25 110003521)	Examiner Name	Sheikh			
Sheet 4 of 9	Attorney Docket Number	Day616			

		NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>		
	31	Suzuki et al, Chem. Pharm. Bull., 49(4):373-378 (2001).			
	32	Shah et al, International Journal of Pharmaceutics, 125:99-106 (1995).			
	33	Giunchedi et al, International Journal of Pharmaceutics, 130:41-47 (1996).			
-	Sangalli et al, Boll. Chim. Farmaceutico, 128(7-8):242-247 (1989).  Kuchiki et al, "Stable Solid Dispersion System Against Humidity," Yakuzaigaku, 44(1):31-37 (1984).				
	36	Guichard et al, "A New Formulation of Fenofibrate: Suprabioavailable Tablets," Current Medical Research and Opinion, 16(2):134-138 (2000).			
	37	Boullay, "Microgrinding and Dissolution," S.T.P. Pharma, 1(4):296-299 (1985). (French-language document and English language translation).	<b>✓</b>		
	38	International Dictionary of Medicine and Biology, Volume 2, page 1774, John Wiley & Sons, Inc. (1986).			
	Opposition to EP 952 829 by Winthrop Arzneimitel GmbH filed March 31, 2005.				
	40	Opposition to EP 952 829 by Laboratoires SMB SA filed April 11, 2005.			

Examiner	Date	
Signature	Considered	

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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	41	Papers filed on April 15, 2005, by Ethypharm in Response to Patent Proprietor's Statement of Opposition to EP 952 829.	
	42	Opposition to EP 0 952 829 by Ethypharm filed December 11, 2003.	✓
	43	Handbook of Pharmaceutical Excipients, Second Edition, pages 392-399 (1994).	
	44	Complaint, US District Court for the District of Delaware, Civil Action No. 04-350, Reliant Pharmaceuticals v. Abbott Laboratories et al (June 1, 2004).	
		Declaration under 37 CFR 1.132 by Pascale Bloquin filed in US Application No. 09/899,026 on March 7, 2005.	
		Laboratoires Fournier's Lab Notebook No. 1 (attached as Exhibit 1 (French) and Exhibit 3 (English translation) to the 132 Declaration by Bloquin).	✓
		Laboratoires Fournier's Lab Notebook No. 2 (attaches as Exhibit 2 (French) and Exhibit 4 (English translation) to the 132 Declaration by Bloquin).	✓
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**Examiner Name** 

STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheikh Sheet 6 of 9 **Attorney Docket Number** aa <

Examiner	Cite	Document Number	Publication Date	DOCUMENTS  Name of Patentee or	Pages, Columns, Lines, Where
Initials* No.1	Number-Kind Code <sup>2 (# known)</sup>	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	
		<sup>US-</sup> 6,027,747	02-22-2000	Terracol et al	
		<sup>US-</sup> 5,633,015	05-27-1997	Gillis et al	
		<sup>US-</sup> 5,145,684	09-08-1992	Liversidge et al	
		<sup>US-</sup> 4,629,624	12-16-1986	Grouiller et al	
		<sup>US-</sup> 4,344,934	08-17-1982	Martin et al	
		<sup>US-</sup> 2005/0032878 A1	02-10-2005	Deboeck et al	
		<sup>US-</sup> 4,961,890	10-09-1990	Boyer	
		<sup>US-</sup> 6,159,499	12-12-2000	Seth	
		<sup>US-</sup> 6,207,198	03-27-2001	Seth	
		<sup>US-</sup> 6,248,355	06-19-2001	Seth	
		<sup>US-</sup> 4,795,643	01-03-1989	Seth	
		<sup>US-</sup> 5,824,341	10-20-1998	Seth et al	
		<sup>US-</sup> 6,096,341	08-01-2000	Seth	
		<sup>US-</sup> 6,033,686	03-07-2000	Seth	
		us- 6,048,547	04-11-2000	Seth et al	
		<sup>US-</sup> 6,117,453	09-12-2000	Seth et al	
		<sup>US-</sup> 6,348,469	02-19-2002	Seth	
		<sup>US-</sup> 4,463,743	03-13-1984	Schonafinger et al	
		<sup>US-</sup> 4,716,033	12-29-1987	Denick, Jr.	

		FORE	IGN PATENT DOCL	MENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	Τ°
	ļ	CA 2,142,848	03-17-1994	Janssen Pharmaceuticals	_	
		CA 960,670	01-07-1975	Orchimed SA		
		WO 98/31360	07-23-1998	Pharma Pass		
		WO 97/12581	04-10-1997	Pharma Pass		
		CA 2,219,475	07-09-2002	Laboratoires Fournier		
		CA 2,372,576	02-10-2004	Laboratoires Fournier		

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INICODMA	TION DISCLOSURE	Filing Date	September 22, 2003	
		First Named inventor	Stamm	
		Art Unit	1615	
(Use as	s many sheets as necessary)	Examiner Name	Sheikh	
Sheet 7	(Use as many sheets as necessary)	Attorney Docket Number	224616	

Examiner Initials*		Number-Kind Code <sup>2 (# known)</sup>		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		<sup>US-</sup> 4,588,058	12-10-1985	Schonafinger et al	
		<sup>US-</sup> 4,957,746	09-18-1990	Valducci	
		<sup>US-</sup> 4,806,361	02-21-1989	Harrison et al	
		<sup>US-</sup> 4,820,521	04-11-1989	Panoz et al	
		<sup>US-</sup> 4,663,150	05-05-1987	Panoz et al	
		<sup>US-</sup> 2,953,497	09-20-1960	Press	
		<sup>US-</sup> 4,524,060	06-18-1985	Mughal et al	
		<sup>US-</sup> 4,721,709	01-26-1988	Seth et al	
		<sup>US-</sup> 5,073,379	12-17-1991	Klimesch et al	
		<sup>US-</sup> 4,684,516	08-1987	Bhutani	
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 	FORE	IGN PATENT DOCL	IMENTS		
Cite No.1	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
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	WO 96/21439	07-18-1996	Galephar PR Inc.		
	WO 03/013500	02-20-2003	Laboratoires SMB SA		
	EP 0 012 523	06-25-1980	American Home Products		L
	WO 97/12580	04-10-1997	Pharma Pass		
	EP 0 179 583	04-30-1986	Merck & Co.		
	EP 0 193 958	09-10-1986	PPG Industries, Inc.		Г

Examiner	Date	
Signature	Considered	

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Sheet 8

Application Number	10/605,520
Filing Date	September 22, 2003
First Named Inventor	Stamm
Art Unit	1615
Examiner Name	Sheikh

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		WO 96/04892	02-22-1996	Pharma Pass		
		WO 98/31361	07-23-1998	Stamm et al		
		WO 96/01621	01-25-1996	Stubberud et al		
		WO 82/01649	05-27-1982	Laruelle		
		EP 0 952 829	03-05-2003	Stamm et al		
		EP 0 761 208	03-12-1997	Duclos et al		

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of 19

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	EP 0 122 077	10-17-1984	Elan Corp.		
	EP 0 164 959	12-18-1985	Sterwin AG		
	EP 0 168 360	01-15-1986	Valducci		
	EP 0 239 541	09-30-1987	Warner-Lambert Co.		
	EP 0 256 933	02-24-1988	Ethypharm		
		Cite No.1  Foreign Patent Document  Country Code3 Number 4 Kind Code5 (if known)  EP 0 122 077  EP 0 164 959  EP 0 168 360  EP 0 239 541	Cite No.1         Foreign Patent Document         Publication Date MM-DD-YYYY           Country Code³ Number⁴ Kind Code⁵ (if known)         10-17-1984           EP 0 164 959         12-18-1985           EP 0 168 360         01-15-1986           EP 0 239 541         09-30-1987	No.1   Date   MM-DD-YYYY	Cite No.1         Foreign Patent Document         Publication Date MM-DD-YYYY         Name of Patentee or Applicant of Cited Document         Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear           EP 0 122 077         10-17-1984         Elan Corp.           EP 0 164 959         12-18-1985         Sterwin AG           EP 0 168 360         01-15-1986         Valducci           EP 0 239 541         09-30-1987         Warner-Lambert Co.

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PTO/SB/17 (12-0-02)
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FEE TRANSMITTAL For FY 2006  Applicant claims small entity status. See 37 CFR 1.27  TOTAL AMOUNT OF PAYMENT  (\$) 180.00  Attorney Docket No. 31672-224616  METHOD OF PAYMENT (check all that apply)  Check Credit Card Money Order None Other (please identify):  X Deposit Account Deposit Account Number: 22-0261 Deposit Account Name: Venable LLP  For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)  X Charge fee(s) indicated below Charge fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17  FEE CALCULATION (All the fees below are due upon filing or may be subject to a surcharge.)  1. BASIC FILING, SEARCH, AND EXAMINATION FEES  FILING FEES  Small Entity Fee (\$) Fee	Ellective on 1200/2004.		
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listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50	listings under 37 CFF		
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Name (Print/Type) Edward D. Grieff Date May 9, 2006			
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